

## REMARKS

Claims 8, 14, 30, 34, and 60-62 are pending in the application.

Claims 8, 14, 30, 34, and 61 are allowed.

Claims 10-13, 15, 32, 33, and 35 have been cancelled without prejudice.

Applicants reserve their right to file a divisional and/or continuation application based on the presently cancelled claims.

Claim 60 has been amended.

Applicant acknowledges the Examiner's approval of the proposed drawing correction to FIG. 5A (Paper No. 10).

### **I. Amended Claim 60.**

Claim 60 has been amended to recite a single member (SEQ ID NO:1) of the Markush group included in the original claim. No new matter is added by this amendment.

### **II. The Specification is in Proper Form.**

The specification was objected to for including text that could be interpreted as a hyperlink (i.e. <http://www.informatics.jax.org>) on page 74, line 25. The paragraph on page 74, line 16-25 has been amended to remove the character string "http://" so that this URL reference will not be mistaken for an active hyperlink. The specification is deemed to be in proper form.

### **III. Claims 60 and 62 Comply With All Requirements of 35 U.S.C. §§101 and 112.**

Claims 60 and 62 stand rejected under 35 U.S.C. §101 as being not supported by either a specific and substantial asserted utility or a well established utility. These claims were also rejected under 35 U.S.C. §112, first paragraph, on the basis that one of skill in the art would not know how to use an invention that does not have a known or asserted specific utility.

As currently amended, claim 60 is directed to a polypeptide of SEQ ID NO:1, a member of the Markush group recited in allowed claim 8. By allowing claim 8, the Examiner has acknowledged the asserted utility for a polypeptide comprising the amino acid sequence of SEQ ID NO:1. Therefore, Claim 60 complies with both §101 and §112, first paragraph, and this rejection should be withdrawn.

Claim 62 is directed to a polypeptide comprising SEQ ID NO:8. The Office Action asserts that there is no specific and substantial utility stated in the application for this polypeptide. Applicants respectfully traverse this assertion. SEQ ID NO:8 corresponds to hcr1 matured by peptidylglycine alpha-amidating monooxygenase, leaving the nitrogen of the terminal glycine as a C-terminal amide (see specification, page 73, lines 5-8). The specification asserts that hcr1 and hcr2 (SEQ ID NO:9) are structurally related to each other and that both polypeptides are related to the hormone secretin (see the specification at page 72, lines 10-14, and page 73, lines 1-17). As acknowledged by the Examiner in allowing claims 8, 14, 30, 34, and 61, hcr2 (SEQ ID NO:9) has a specific utility of suppressing food intake following intracerebroventricular administration. (Paper No. 13, page 4).

Members of the secretin family of gastrointestinal hormones have well established utility. Prior to the earliest filing date of the present application (e.g., August 2, 1996) secretin was known to be a gastrointestinal hormone secreted by the pancreas, and involved in digestion. Secretin also was known to be structurally related to certain other gastrointestinal hormones including glucagon, gastric inhibitory peptide (GIP), vasoactive intestinal polypeptide (VIP), peptide histidine isoleucine (PHI), and peptide histidine methionine (PHM), which are collectively known as the secretin family of hormones. (See *Basic & Clinical Endocrinology*, Fourth Edition, Greenspan and Baxter (Eds.), pp. 551-558, particularly pages 557-558, Appleton & Lange, Norwalk, CN (1994), a copy of which is attached hereto).

The structural similarity of hcr1 to hcr2 (having demonstrated utility in gastrointestinal regulation) and to secretin (having well known gastrointestinal function) provides sufficient basis to assert that one of ordinary skill in the art would have recognized the utility of a new secretin-related polypeptide such as hcr1 and its analogs. This is particularly true in light of the existence of a whole family of gastrointestinal hormones related to secretin. Additionally, the specification states that the hcr polypeptides of the invention are hypocretin receptor ligands and have the ability to inhibit hypocretin receptor binding (see page 16, lines 13-21). As noted above, Example 7 demonstrates the utility of inhibiting hypocretin function. The specification also states that hcr polypeptides can be used to generate antibodies to hypocretin (page 20, lines 2-9) which, in turn, are useful for

clinically assaying for hypocretin function. Therefore, ample and specific utility of hcr1 and related polypeptides are asserted in the specification and this rejection should be withdrawn.

Claim 60 has also been rejected under 35 U.S.C. §112, second paragraph as being indefinite since the claim was partly directed to non-elected subject matter (i.e., SEQ ID NO:2). The present amendment to the claim renders this ground for rejection moot and the rejection should be withdrawn.

**IV. Conclusion.**

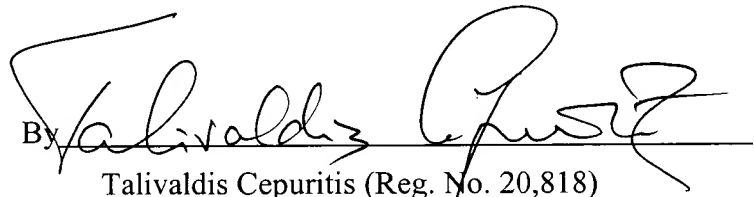
Claims 8, 14, 30, 34, and 61 have been allowed. Claims 60 and 62 are now deemed to satisfy all requirements of 35 U.S.C. §§ 101 and 112. Therefore, Applicants respectfully request that all of the pending claims be allowed and that an Interference be declared between the present application and U.S. Patent No. 6,001,963.

Respectfully submitted,

Dated

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By



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